Phillip Wm. Lear
Lear & Lear PLLC
808 E South Temple Street
Salt Lake City, UT 84102
Telephone: (801) 538-5000
Facsimile:(801) 538-5001
Email: phillip.lear@learlaw.com
Local Attorney for Linda P. Smith

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH
CENTRAL DIVISION

LINDA P. SMITH,

Plaintiff

v.

XAVIER BECERRA, in his capacity as the Secretary of the United States Department of Health and Human Services,

Defendant

Case No. 1:21-cv-00047-HCN-DBP

PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT BASED ON COLLATERAL ESTOPPEL

JURY TRIAL DEMANDED

Judge Howard Nielson, Jr.
Magistrate Judge Dustin B. Pead

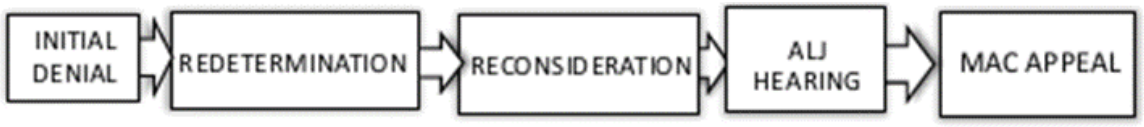
I. Introduction and Relief Sought

Pursuant to FED.R.CIV.P. 56, DUCivR 56-1, and 5 U.S.C. § 706(2)(A)/(C)/(E) (*see* Dkt. #2, Counts I, II, and IV), Mrs. Smith files this motion for summary judgment that the claims in this case are covered "durable medical equipment" and that the Secretary is barred from contesting the same based on collateral estoppel. Mrs. Smith seeks a judgment reversing the Secretary's denials, finding that her claims are covered, and a remand to the Secretary (pursuant to 42 U.S.C. § 405(g) (fourth sentence) with instructions to cover the claims at issue.

II. Background

As detailed in the Complaint, Mrs. Smith is a 76-year old mother of five, grandmother to 19, wife of more than 50 years to husband Kent, and a former high school English Teacher. *See* Complaint at ¶ 47. Mrs. Smith is a Type I, "brittle" diabetic. In addition, Mrs. Smith suffers from hyper/hypoglycemic unawareness. *Id*. at ¶ 48.

1. The Medicare Appeal Process



Claims submitted by beneficiaries enrolled in Medicare are subject to a five-level appeal process that typically takes more than a year. At issue at each stage of the process is whether the claim is a Medicare covered benefit/is medically

reasonable and necessary for the beneficiary. The beneficiary begins by submitting a claim. *See* 42 C.F.R. §§ 405.920-928. If that is denied, the beneficiary can request "redetermination." *See* 42 C.F.R. §§ 405.940-958. If the claim is still denied, the beneficiary can request "reconsideration." *See* 42 C.F.R. §§ 405.960-978.

If the claim is still denied, the Secretary must provide "hearings" for appeals to the "same extent" as is provided for in Social Security hearings. *See* 42 U.S.C. § 1395ff(b)(1)(A) (citing 42 U.S.C. § 405(b)). That is, in conducting the hearings, the Secretary is authorized to administer oaths, examine witnesses, and receive evidence.

The Secretary has promulgated regulations concerning the conduct of the "hearing" by ALJs. *See* 42 C.F.R. §§ 405.1000-1058. At a minimum, in cases where the beneficiary is represented by counsel, the hearings are adversarial. In such cases, the Secretary's representative (in the form of the Centers for Medicare and Medicaid Services (CMS) or a contractor to Medicare) has the opportunity to litigate. *See* 42 C.F.R. §§ 405.1008 & 405.1010.

In that capacity, the Secretary (like the beneficiary) can submit evidence (42 C.F.R. § 405.1018), object to the timing of the hearing (42 C.F.R. § 405.1020), object to issues before the ALJ (42 C.F.R. § 405.1024); object to the assigned ALJ (42 C.F.R. § 405.1026); take discovery (42 C.F.R. § 405.1037); present evidence in

the form of documents and witnesses (including through subpoenas), cross-examine witnesses, and present argument (42 C.F.R. § 405.1036).

Regardless of whether the Secretary's representative appears, the beneficiary bears the burden of proving entitlement to benefits. *See, e.g.*, AR26 ("The Appellant bears the burden of proving each element of the Medicare claim."). After the hearing, the ALJ issues a written decision, which includes findings of fact, conclusions of law, and reasons for the decision and must be based on the evidence admitted at the hearing. *See* 42 C.F.R. § 405.1046. Absent an appeal within 60 days, the ALJ's decision is binding and represents the final decision of the Secretary. *See* 42 C.F.R. §§ 405.1048(a); 405.1110(a).

Like the beneficiary, if the Secretary is dissatisfied with the ALJ's decision, the Secretary can appeal to the Medicare Appeals Council (MAC).[1] *See* 42 C.F.R. §§ 405.1100-1140. Indeed, regardless of whether the Secretary participates in the hearing, the Secretary can appeal an ALJ's decision on so-called "own motion" review. *See* 42 C.F.R. § 405.1110. Finally, if the beneficiary is dissatisfied with the Council's decision, he or she can seek judicial review. *See* 42 U.S.C. § 1395ff(b)(1)(A) (citing 42 U.S.C. § 405(g)).

[1] This is also known as the Departmental Appeals Board (DAB).

2. The Prior ALJ Decision and The Decision(s) at Issue in This Case

After an appeal by CMS of a fully favorable decision by ALJ Lambert to the MAC, the MAC vacated ALJ Lambert's decision and remanded for further proceedings. *See* AR1405. Thereafter, on April 4, 2018, ALJ Lambert held an additional hearing at which Mrs. Smith and her counsel (Debra Parrish) appeared. *Id.* ("An administrative law judge telephone hearing was held on April 4, 2018, at 2:30 PM EST in Cleveland, Ohio. Debra Parrish, Esq., the Appellant's Counsel and Linda Smith appear on behalf of Appellant."). ALJ Lambert stated: "The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council." *Id*.

ALJ Lambert found that Mrs. Smith's CGM (and supplies) met Medicare coverage criteria and were reasonable and necessary. *See* AR1410 ("The Appellant argues continuous glucose monitor sensors (A9276) at issue met Medicare coverage criteria and were reasonable and necessary. The ALJ agrees with the Appellant."). ALJ Lambert further found that CGMs are "primarily and customarily used to serve a medical purpose." *Id.* ("Continuous glucose monitors are primarily and customarily used to serve a medical purpose."); AR1411 ("Thus, the AL finds that the continuous glucose monitor that the Appellant owns is primarily and customarily used to serve a medical purpose"). ALJ Lambert found that Mrs. Smith's CGM (and supplies) was "durable medical equipment." *See* AR1408-1411.

ALJ Lambert further found that Mrs. Smith's CGM (and supplies) are medically reasonable and necessary and met Medicare criteria for coverage. AR1411 ("In addition, the ALJ find the continuous glucose monitor sensors are reasonable and necessary."); ("Accordingly, the ALJ finds that the continuous glucose monitor sensors (A89276) at issue were reasonable and necessary and met Medicare coverage criteria for reimbursement.").

> The Appellant satisfied the applicable coverage criteria for reimbursement under Part B of the Act for the continuous glucose monitors sensors (A9276) that it furnished to the Beneficiary on October 29, 2016. Therefore, as a matter of law, the continuous glucose monitor sensors (A9276) furnished on the above date were reasonable and necessary under § 1862(a) of the Act, and the documentation requirements of § 1833€ were sufficiently satisfied for Medicare to provide reimbursement.

Id.

With regard to the claims at issue in this case, ALJ Win found that in order to meet CMS definition of "primarily and customarily used to serve a medical purpose" as defined in CMS 1682-R, a CGM had to replace a blood glucose monitor. *See, e.g.*, AR31. ALJ Win also found that Mrs. Smith's CGM (and supplies) was not intended as a replacement for a blood glucose monitor and was not "therapeutic." *See* AR10-11. ALJ Win found that Mrs. Smith's CGM (and supplies) was not "durable medical equipment" and was not a Medicare covered benefit. *See* AR8-10.

The MAC "adopted" ALJ Win's decisions in both cases. See AR3 ("[W]e adopt the ALJ's decisions."); AR11 ("The ALJ's decision is adopted."). Further, the

MAC found that Mrs. Smith's CGM (and supplies) was not "primarily and customarily used to serve a medical purpose." See AR10-11 ("non-therapeutic"); ("only CGM devices serving to provide or guide therapy directly are understood to be primarily and customarily used to serve a medical purpose under Medicare.").

The MAC also determined that Mrs. Smith's CGM (and supplies) were not "durable medical equipment" and not a Medicare covered benefit. *See* AR10-11.

III. Statement of Undisputed Material Facts

In adjudicating claims before them, Medicare ALJs and the MAC are acting in a judicial capacity. *See, e.g.*, AR1405-1412.

Mrs. Smith was represented in the litigation before ALJ Lambert. *See* AR1405.

In the litigation before ALJ Lambert, Mrs. Smith bore the burden of proving entitlement to Medicare coverage. *See* AR26.

The Secretary did not appeal ALJ Lambert's April 24, 2018, decision. *See* Exhibit A at ¶4. Exhibit B at ¶74, Exhibit C at ¶74.

The Secretary had a full and fair opportunity to litigate before ALJ Lambert. *See* AR1405; Exhibit B at ¶ 65; Exhibit C at ¶ 65.

ALJ Lambert determined that Mrs. Smith's CGM (and supplies) were "durable medical equipment", "primarily and customarily used to serve a medical

purpose", "medically reasonable and necessary", and a covered Medicare benefit. *See* AR1410; AR1411; AR1406.

ALJ Lambert's determination that Mrs. Smith's CGM (and supplies) were "durable medical equipment", "primarily and customarily used to serve a medical purpose", "medically reasonable and necessary" were a necessary component to finding Medicare coverage. *See* AR1405-1412.

ALJ Lambert's decision became final on or after June 25, 2018. *See* Exhibit B at ¶74; Exhibit C at ¶74.

ALJ Win found that Mrs. Smith's CGM was not "durable medical equipment." *See* AR30-32.

ALJ Win found that Mrs. Smith's CGM was not "durable medical equipment" and not a Medicare covered benefit. *See* AR30-32.

The MAC adopted ALJ Win's decisions in both appeals. *See* AR3; AR11.

The MAC found that Mrs. Smith's CGM (and supplies) were not "primarily and customarily used to serve a medical purpose." *See* AR10-11.

The MAC found that Mrs. Smith's CGM (and supplies) were not "durable medical equipment." *See* AR10-11.

The MAC found that Mrs. Smith's CGM (and supplies) were not covered Medicare benefits. *See* AR10-11.

IV. Argument

As detailed above and below, after a full litigation on the merits, Mrs. Smith received one ALJ decision (from ALJ Lambert) finding that her CGM (and supplies) is "durable medical equipment" and a covered Medicare benefit. Subsequently, another ALJ (and the MAC) arrived at the opposite conclusion. Avoiding the burden of repeated litigation on the parties and the judiciary as well as inconsistent results are the very purposes of collateral estoppel and collateral estoppel should be applied here.

A. The Complaint and the Secretary's "Answer"

Pursuant to FED.R.CIV.P. 8(b)(1)(B), a party must admit or deny the allegations asserted against it. Any denials must "fairly respond to the substance of the allegation" (FED.R.CIV.P. 8(b)(2)) and must also be in good faith (in addition to complying with other obligations under the Rules). In addition, if only part of an allegation can be denied in good faith, the defendant must deny only that part and must admit the rest. *See* FED.R.CIV.P. 8(b)(4). A claim that a party lacks knowledge or information to form a belief about the truth of an allegation has the effect of a denial. *See* FED.R.CIV.P. 8(b)(5). If a party fails to deny an allegation, the allegation is deemed admitted. *See* FED.R.CIV.P. 8(b)(6). Importantly, deeming matters admitted as a result of a failure to properly deny is not a sanction. Instead, it is merely the operation of the Rules. *See, e.g., Perez v. El Tequila, LLC.*, 847 F.3d 1247, 1254 (10th Cir. 2017).

With regard to collateral estoppel, the relevant allegations of the Complaint are found at ¶¶ 64-95. *See* Exhibit B. The allegations of the Complaint and the response of the "Answer" (see Exhibit C) are summarized as follows:

Complaint	**"Answer"**
¶ 64 – Mrs. Smith was represented by her counsel during the hearing held on April 4, 2018, by ALJ Lambert.	Either no response or a claim of lack of sufficient knowledge or information.
¶ 65 – The Secretary had a full and fair opportunity to litigate before ALJ Lambert.	Claim of lack of sufficient knowledge or information.
¶ 66 – Allegation of specific issues litigated before ALJ Lambert.	No clear admission or denial.
¶ 68 – Allegation that ALJ Lambert found that Mrs. Smith's CGM (and supplies) was "primarily and customarily used to serve a medical purpose."	No clear admission or denial.
¶ 69 – Allegation that ALJ Lambert found that Mrs. Smith's CGM (and supplies) was "durable medical equipment."	No clear admission or denial.
¶ 70 – Allegation that ALJ Lambert found that Mrs. Smith's CGM (and supplies) was "medically reasonable and necessary."	No clear admission or denial.
¶ 71 – Allegation that ALJ Lambert found that Mrs. Smith's CGM (and supplies) was covered by Medicare.	No clear admission or denial.
¶ 72 – Allegation that ALJ Lambert's determinations of the issues of ¶¶ 68-70 was a necessary component to finding Medicare coverage.	No clear admission or denial.
¶ 75 – Allegation that ALJ Lambert's decision became final on or after June 25, 2018.	No clear admission or denial.

¶ 84 – Allegation that ALJ Win found that Mrs. Smith's CGM (and supplies) was not "durable medical equipment" as defined in CMS 1682-R.	No clear admission or denial.
¶ 90 – Allegation that ALJ Win found that Mrs. Smith's CGM (and supplies) was not "durable medical equipment" as defined in CMS 1682-R and not a Medicare covered benefit.	No clear admission or denial.
¶ 92 – Allegation that the MAC adopted ALJ Win's decisions in both appeals.	No denial that the MAC adopted ALJ Win's decisions.
¶ 94 – Allegation that Mrs. Smith's CGM claims were rejected as not "durable medical equipment" because they were not "primarily and customarily used to serve a medical purpose either as defined in CMS 1682-R or on the grounds they were "precautionary."	No clear admission or denial.
¶ 95 – Allegation that because Mr. Smith's CGM claims did not qualify as "durable medical equipment", they were necessarily excluded from coverage as not "medically reasonable and necessary."	No clear admission or denial.

The "Answer" closes with: "The Secretary denies any and all allegations of the complaint not expressly admitted herein." *See* Exhibit C at 23.

For the purposes of the present motion, given the failure to clearly admit or deny the allegations above, failures to respond to the substance of the allegation in violation of FED.R.CIV.P. 8(b)(2), and/or denials without a good faith basis, all the allegations detailed above should be deemed admitted pursuant to FED.R.CIV.P. 8(b)(6). Alternatively, relying on the general denial or specific denials (including

the claims of lack of knowledge or information), the Court may treat all the allegations as denied (in which case additional motion practice will follow).

B. Collateral Estoppel Applies to Medicare Cases

Collateral estoppel applies against the United States the same as any litigant and final judgments of agencies acting in a judicial capacity have the same effect as a judgment of a court. Thus, when the Secretary has a fair opportunity to litigate but loses a coverage case before one of his own ALJs, the Secretary is collateral estopped from relitigating identical issues in future cases brought by the same party. *See Astoria*, 501 U.S. at 107 ("a losing litigant deserves no rematch after a defeat fairly suffered").

1. Collateral Estoppel Generally

Collateral estoppel is a bedrock common law doctrine that bars re-litigation of a legal or fact issue determined in a prior proceeding. Under the doctrine, "once an issue is actually and necessarily determined by a court of competent jurisdiction, that determination is conclusive in subsequent suits based on a different cause of action involving a party to the prior litigation." *Montana v. U.S.*, 440 U.S. 147, 153-54 (1979).

Collateral estoppel serves the triple purposes of protecting litigants from the burden of relitigating an identical issue, promoting judicial economy by preventing needless litigation, and encouraging reliance on adjudication by preventing

inconsistent results. *See Allen v. McCurry*, 449 U.S. 90, 94 (1980); *Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322, 326 (1979).

Because of the United States' unique posture as a litigant, the Supreme Court has held that only mutual collateral estoppel applies against the United States. *See U.S. v. Mendoza*, 464 U.S. 154 (1984). Accordingly, only a party to a prior proceeding with the government can assert collateral estoppel against the government.

Proceedings giving rise to collateral estoppel include agency proceedings. In *Astoria*, the Supreme Court held:

> We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality. When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata to enforce repose. Such repose is justified on the sound and obvious principle of judicial policy that a losing litigant deserves no rematch after a defeat fairly suffered, in adversarial proceedings, on an issue identical in substance to the one he subsequently seeks to raise. To hold otherwise would, as a general matter, impose unjustifiably upon those who have already shouldered their burdens, and drain the resources of an adjudicatory system with disputes resisting resolution. The principle holds true when a court has resolved an issue, and should do so equally when the issue has been decided by an administrative agency, be it state or federal, which acts in a judicial capacity.

501 U.S. at 107-8 (internal citations omitted). *See also B & B Hardware,* 575 U.S. 148-151 (confirming presumption that administrative decisions are subject to issue preclusion).

2. There Is a Presumption that Collateral Estoppel Applies When an Agency Is Acting in a Judicial Capacity

As set forth in *Astoria*, there is a presumption that common law principles (including collateral estoppel) apply to administrative decisions where an agency is acting in a "judicial capacity." *Astoria*, 501 U.S at 108 ("where a common-law principle is well established, as are the rules of preclusion, the courts may take it is as given that Congress has legislated with an expectation that the principle will apply except when a statutory purpose to the contrary is evident."). A party asserting that collateral estoppel does not apply bears the burden of establishing that the presumption has been overcome. *See Green v. Bock Laundry Machine Co.*, 490 U.S. 504, 521 (1989) ("has the burden of showing that the legislature intended such a change.").

To overcome the presumption of the common law, a party must demonstrate that Congress clearly evidenced an intent to do so. *Astoria*, 501 U.S. at 109-110; *U.S. v. Texas*, 507 U.S. at 535 ("an expression of legislative intent to supplant"); *Green*, 490 U.S. at 521 (must show "legislature intended such a change").

Moreover, to overcome the presumption, a statute must "speak directly" to the common law issue. *See Texas*, 507 U.S. at 534. Statutes which are compatible with

the pre-existing practice of the common law do not overcome the presumption. *See BFP v. Resolution Trust Corp.*, 511 U.S. 531, 543 (1994) ("a phrase entirely compatible with pre-existing practice").

Numerous cases have affirmed the application of collateral estoppel based on agency determinations (including against agencies). *See Continental Can Co., U.S.A., v. Marshall*, 603 F.2d 590 (7th Cir. 1979) (DOL collaterally estopped by prior decisions of department); *Bowen v. U.S.*, 570 F.2d 1311, 1321-23 (7th Cir. 1978) (NTSB acting in judicial capacity in prior proceeding, plaintiff collaterally estopped); *Drummond v. Comm'r of Social Security*, 126 F.3d 837, 841-43 (6th Cir. 1997) (SSA collaterally estopped by prior ALJ work determination); *C & N Corp. v. Kane*, 953 F. Supp. 2d 903, 912-14 (E.D. Wisc. 2013) (defendant collaterally estopped by prior TTAB proceeding); *Islam v. U.S. D.H.S.*, 136 F. Supp. 3d 1088 (N.D. Cal. 2015) (D.H.S. collaterally estopped by prior immigration judge's determination). *See also DeWall Enterprises, Inc. v. Thompson*, 206 F. Supp. 2d 992, 1001 (D. Neb. 2002) ("The Secretary's assertions that the ALJ's decisions are not afforded any preclusive effect are without merit.").

Under Tenth Circuit law, the party invoking the doctrine of collateral estoppel has he burden of establishing four elements: 1) the issue previously decided is identical with the one presented in the action in question; 2) the prior action has been finally litigated on the merits; 3) the party against whom

the doctrine is invoked was a party or in privity with a party to the prior adjudication, and 4) the party against whom the doctrine is raised had a full and fair opportunity to litigate the issue in the prior action. *See Stan Lee Media, Inc. v. Walt Disney Co.*, 774 F.3d 1292, 1297 (10th Cir. 2014). In addition, the issue previously decided must have been essential to the judgment. *Id.*

Here, the Secretary is indisputably acting in a "judicial capacity" when conducting hearings before his ALJs or the MAC. *See, e.g.,* AR1405-1412. Thus, collateral estoppel applies to Medicare cases unless the Secretary can overcome the presumption by identifying statutes evidencing Congress' "clearly expressed" intention to abrogate the common law. That is a burden the Secretary cannot meet and collateral estoppel applies to Medicare cases.

C. Collateral Estoppel Applies in this Case

There is no genuine issue of material fact that all the elements prescribed for the application of collateral estoppel in *Stan Lee* are present in this case and the Secretary is collaterally estopped from denying coverage. The purposes of collateral estoppel in avoiding the burden of re-litigation on Mrs. Smith, the burden on the judiciary (including before the Secretary), and the prosect of inconsistent results are served by applying collateral estoppel in this case. *Allen*, 449 U.S. at 94; *Parklane*, 439 U.S. at 326.

1. The Issue Previously Decided Is Identical With the One Presented

As detailed above, the fundamental issue of whether Mrs. Smith's CGM (and supplies) is a covered Medicare benefit was decided by ALJ Lambert in Mrs. Smtih's favor. *See* AR1405-1412. The identical issue was decided in ALJ Win's decisions and the MAC decision denying Mrs. Smith's claims. *See* AR10-11.

Further, the sub-issues of whether Mrs. Smith's CGM (and supplies) were "durable medical equipment", "medically reasonable and necessary", and "primarily and customarily used for a medical purpose" were decided by ALJ Lambert in Mrs. Smith's favor. *See* AR1405-1412. The identical issues were decided in ALJ Win's decisions and in the MAC decision that both "adopted" ALJ Win's decisions and made its own findings in finding against Mrs. Smith's claim. See AR3; AR11.

Accordingly, the issue(s) previously decided is/are identical to the one(s) decided in the prior litigation.

2. The Prior Action Has Been Fully Litigated on the Merits

There is no genuine issue of material facts that the litigation before ALJ Lambert has been fully litigated on the merits. In the proceedings before ALJ

Lambert, Mrs. Smith bore the burden of proof, which she sustained in ALJ Lambert's decision finding coverage. *See* AR26; AR1405-1412.

Pursuant to 42 C.F.R. §§ 405.1048(a) and 405.1110(a), if an ALJ decision in not appealed within 60 days, the ALJ decision is the Secretary's final decision and is binding. *See also, e.g.*, AR1407 ("The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council.").

The Secretary admits that he did not appeal ALJ Lambert's decision. *See* Exhibit B at ¶74, Exhibit C at ¶74. Thus, by operation of the Secretary's own regulations, ALJ Lambert's decision became final no later than June 25, 2018. With regard to whether ALJ Lambert's decision became final on or after June 25, 2018, the Secretary failed to deny that allegation and it is deemed admitted. *See* Exhibit B at ¶75, Exhibit C at ¶75. Alternatively, there is no evidence from which a reasonable trier of fact could conclude that ALJ Lambert's decision is not final.

3. The Party Against Whom the Doctrine Was Invoked Was A Party or in Privity With a Party to the Prior Adjudication

As a hearing before the Secretary in which Mrs. Smith bore the burden of proof, the Secretary was a party to the litigation before ALJ Lambert. *See*

AR26; AR1405-1412. Given Mrs. Smith's representation by counsel, the Secretary had the full panoply of rights of a litigant. *See* AR1405..

4. The Party Against Whom the Doctrine Is Raised Had a Full and Fair Opportunity to Litigate the Issue in the Prior Action

As detailed above, Mrs. Smith was represented in the action before ALJ Lambert. *See* AR1405. With regard to this fact, respectfully, Mrs. Smith believes that the Secretary's denial based on alleged "lack of sufficient knowledge or information" is in bad faith and that this fact should be deemed admitted. *See* Exhibit B at ¶64, Exhibit C at ¶64. Nevertheless, the evidence is that Mrs. Smith was represented in the action before ALJ Lambert and there is no evidence from which a reasonable trier of fact could conclude otherwise.

As a result, there is no genuine issue of material fact that the Secretary had a full and fair opportunity to litigate before ALJ Lambert. As detailed above, under the Secretary's own regulations, when a beneficiary is represented, the Secretary has all the rights of a litigant (including the right to call witnesses, cross-examine, etc.). With regard to whether the Secretary had a full and fair opportunity to litigate before ALJ Lambert, the Secretary failed to deny that allegation and it is deemed admitted. *See* also Exhibit B at ¶65, Exhibit C at ¶65. Alternatively, there is no evidence from which a reasonable

trier of fact could find that the Secretary did not have a full and fair opportunity to litigate before ALJ Lambert.

5. The Issue Previously Decided Was Essential to the Judgment

Of course, the base issue decided by ALJ Lambert was whether Mrs. Smith's CGM (and supplies) were covered Medicare benefits and that determination was essential the judgment in her favor. *See* AR1405-1412. Moreover, necessary components of that decision are the sub-issues of whether the device/service is "medically reasonable and necessary" and fits within a Medicare benefit category (*i.e.*, is "durable medical equipment"). A necessary component of finding that a CGM is "durable medical equipment" is a finding that a CGM is "primarily and customarily used to serve a medical purpose."

Thus, the issue(s) previously decided was/were essential to ALJ Lambert's judgment.

V. Conclusion

For the reasons set forth above, the Court should reverse the Secretary's denials, find that the Secretary is collaterally estopped from denying that Mrs. Smith's claims in this case are covered, and should enter judgment in Mrs. Smith's favor. Pursuant to 42 U.S.C. § 405(g) (fourth sentence), the Court

should remand this matter to the Secretary with instructions to cover the claims at issue.

Dated: September 7, 2021

Respectfully submitted,

PARRISH LAW OFFICES

/s/ James C. Pistorino
James C. Pistorino
Attorneys for Plaintiffs

LEAR & LEAR PLLC

/s/ Phillip Wm. Lear
Phillip Wm. Lear
Attorneys for Plaintiff